

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 09653	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2004/008699	International filing date (day/month/year) 15.06.2004	Priority date (day/month/year) 16.06.2003
International Patent Classification (IPC) or national classification and IPC		
Applicant TAKEDA PHARMACEUTICAL COMPANY LIMITED		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>9</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>4</u> sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input checked="" type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s))</p> <p><u>1 disk</u>, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>																									
<p>4. This report contains indications relating to the following items:</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>		<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VIII	Certain observations on the international application
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Date of submission of the demand	Date of completion of this report																								
Name and mailing address of the IPEA/JP	Authorized officer																								
Facsimile No.	Telephone No.																								

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
 - ☐ publication of the international application (Rule 12.4)
 - ☐ international preliminary examination (Rule 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- ☐ the international application as originally filed/furnished
- ☒ the description:

pages 1-3, 5-121 as originally filed/furnished

pages* 4 received by this Authority on 24.01.2005

pages* _____ received by this Authority on _____

- ☒ the claims:
- nos. 1-4, 6-44 as originally filed/furnished

nos.* _____ as amended (together with any statement) under Article 19

nos.* 5, 45-51 received by this Authority on 24.01.2005

nos.* _____ received by this Authority on _____

- ☒ the drawings:
- sheets fig. 1-15 as originally filed/furnished

sheets* _____ received by this Authority on _____

sheets* _____ received by this Authority on _____

- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing (*specify*): _____

☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 14, 15, 27, 28, 41, 42 and a portion of claims 1, 3, 6, 10, 16, 19, 23, 31, 33

because:

- ☒ the said international application, or the said claims Nos. 14, 15, 27, 28, 41, 42 relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 14, 15, 27, 28, 41 and 42 pertain to a method for the treatment of the human body by means of therapy, and thus relate to a subject matter for which this International Preliminary Examining Authority is not required to carry out an international preliminary examination under the provisions of PCT Article 17(2) (a) (i) and PCT Rule 39.1(iv).

- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. a portion of claims 1, 3, 6, 10, 16, 19, 23, 31, 33 are so unclear that no meaningful opinion could be formed (*specify*):

Refer to Box VIII.

- ☒ the claims, or said claims Nos. a portion of claims 1, 3, 6, 10, 16, 19, 23, 31, 33 are so inadequately supported by the description that no meaningful opinion could be formed.

- ☒ no international search report has been established for said claims Nos. a portion of claims 1, 3, 6, 10, 16, 19, 23, 31, 33

- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

- ☐ See Supplemental Box for further details.

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-13, 16-26, 29-40, 43-51</u>	YES
	Claims	<u></u>	NO
Inventive step (IS)	Claims	<u>1-13, 16-26, 29-40, 43-51</u>	YES
	Claims	<u></u>	NO
Industrial applicability (IA)	Claims	<u>1-13, 16-26, 29-40, 43-51</u>	YES
	Claims	<u></u>	NO

2. Citations and explanations (Rule 70.7)

The inventions set forth in claims 1 to 13, 16 to 26, 29 to 40 and 43 to 51 are not disclosed in any of the documents that are cited in the international search report, and would not have been obvious to a person skilled in the art; therefore, the inventions in question are novel and involve an inventive step. In particular, the proteins which have the same amino acid sequence as the amino acid sequence subsequent to the first amino acid within the amino acid sequences that are represented by SEQ ID NO: 2 and 4 are not disclosed in any of the documents.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 2003/054005 A2	03.07.2003	20.12.2002	20.12.2001
[PX]			

2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1, 6 and 23

The disclosure "substantially identical" in the abovementioned claims renders the scopes of the inventions that are set forth therein unclear; therefore, the disclosures of the abovementioned claims cannot be said to be sufficiently clear. In other words, the description includes the disclosure "it is possible to present amino acid sequences or the like that have a homology...(omission)...of approximately 70% or more...(omission)...as examples of the substantially identical amino acid sequences" (refer to page 10); however, the inclusion of the disclosures "approximately" and "or the like" renders the scopes of the inventions unclear.

In addition, for example, it is unclear specifically what type of structure is characteristic of the proteins which have an amino acid sequence that exhibits a homology of 70% in relation to the amino acid sequence subsequent to the first amino acid within the amino acid sequences that are represented by SEQ ID NO: 2 and 4 and which also exhibit substantially the same activity as a protein with the amino acid sequence that is represented by SEQ ID NO: 2 or 4, and it would require an excessive amount of trial and error testing for a person skilled in the art to obtain the proteins in question. Therefore, the inventions that are set forth in the abovementioned claims cannot be said to be fully supported by the description, and cannot be said to be disclosed in the description in a manner that is sufficiently clear and complete for the inventions in

Box No. VIII Certain observations on the international application

question to be carried out by a person skilled in the art of the technical field in question.

As a result, an international search was not carried out in relation to the inventions pertaining to the "proteins which have a substantially identical amino acid sequence," which are not clearly set forth in the claims, are not fully supported by the description, and are not supported by the description in a manner that is sufficiently clear and complete.

Claims 3, 6, 10, 16, 19, 23, 31 and 33

It is unclear specifically what portion is being indicated by the disclosure "partial" or "one part" in the abovementioned claims; therefore, the disclosures of the abovementioned claims cannot be said to be sufficiently clear.

In addition, for example, it is unclear specifically what type of structure is characteristic of the peptides which are partial peptides of the amino acid sequence subsequent to the first amino acid within the amino acid sequences that are represented by SEQ ID NO: 2 and 4 and which also exhibit substantially the same activity as a protein with the amino acid sequence that is represented by SEQ ID NO: 2 or 4, and it would require an excessive amount of trial and error testing for a person skilled in the art to obtain the peptides in question. Therefore, the inventions that are set forth in the abovementioned claims cannot be said to be fully supported by the description, and cannot be said to be disclosed in the description in a manner that is sufficiently clear and complete for the inventions in question to be carried out by a person skilled in the art

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of the technical field in question.

As a result, an international search was not carried out in relation to the inventions pertaining to the "partial peptides" or the "nucleic acids that contain one part," which are not clearly set forth in the claims, are not fully supported by the description, and are not supported by the description in a manner that is sufficiently clear and complete.

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."